

**IN THE UNITED STATES BANKRUPTCY COURT
FOR THE DISTRICT OF DELAWARE**

In re:

DERMTECH, INC., *et al.*,¹

Debtors.

Chapter 11

Case No. 24-11378 ([____])

(Joint Administration Requested)

**DEBTORS' MOTION FOR ENTRY OF AN ORDER (I) AUTHORIZING
CERTAIN PROCEDURES TO MAINTAIN THE CONFIDENTIALITY OF
PATIENT INFORMATION AS REQUIRED BY APPLICABLE
PRIVACY RULES; AND (II) GRANTING RELATED RELIEF**

DermTech, Inc. and DermTech Operations, Inc. (each, a “Debtor” and collectively, the “Debtors”), as debtors and debtors in possession in the above-captioned chapter 11 cases, by and through their undersigned proposed counsel, hereby submit this motion (this “Motion”) for entry of an order (the “Proposed Order”), substantially in the form annexed hereto as **Exhibit A**, pursuant to sections 105(a), 107, and 521(a)(1) of title 11 of the United States Code, as amended (the “Bankruptcy Code”), rules 1007, 9018, and 9037 of the Federal Rules of Bankruptcy Procedure (the “Bankruptcy Rules”), and rule 1007-1 of the Local Rules of Bankruptcy Practice and Procedure of the United States Bankruptcy Court for the District of Delaware (the “Local Rules”), authorizing the Debtors to implement certain procedures to maintain the confidentiality of patient information as required by applicable privacy rules. In support of this Motion, the Debtors rely upon the *Declaration of Bret Christensen, President and Chief Executive Officer of the Debtors, in Support of the Debtors' Chapter 11 Petitions and First Day Motions* (the “First

¹ The Debtors in these chapter 11 cases, along with the last four digits of each Debtor’s federal tax identification number are: DermTech Inc. (0849) and DermTech Operations, Inc. (8997). The Debtors’ service address is 12340 El Camino Real, San Diego, California 92130.

Day Declaration”), filed concurrently herewith and incorporated herein by reference.² In further support of this Motion, the Debtors respectfully represent as follows:

JURISDICTION

1. The Court has jurisdiction to consider this Motion under 28 U.S.C. §§ 157 and 1334 and the *Amended Standing Order of Reference* from the United States District Court for the District of Delaware dated February 29, 2012. Pursuant to Local Rule 9013-1(f), the Debtors confirm their consent to the entry of a final order by the Court in connection with the Motion to the extent that it is later determined that the Court, absent consent of the parties, cannot enter final orders or judgments in connection herewith consistent with Article III of the United States Constitution.

2. This is a core proceeding pursuant to 28 U.S.C. § 157(b). Venue of these chapter 11 cases and this Motion in this district is proper pursuant to 28 U.S.C. §§ 1408 and 1409.

3. The statutory bases for the relief requested herein are sections 105(a), 107, and 521(a)(1) of the Bankruptcy Code, and Bankruptcy Rules 1007, 9018, and 9037.

RELIEF REQUESTED

4. By this Motion, the Debtors seek entry of the Proposed Order establishing certain procedures to maintain the confidentiality of patient information as required by HIPAA.³

BACKGROUND

A. General Background

5. On the date hereof (the “Petition Date”), each Debtor filed a voluntary petition for relief pursuant to chapter 11 of the Bankruptcy Code. The Debtors are operating their businesses

² Capitalized terms used, but not otherwise defined herein, shall have the meanings given to them in the First Day Declaration.

³ For the avoidance of doubt, the Debtors will continue to manage, protect, and utilize protected information in the ordinary course of its business in accordance with HIPAA. The proposed Privacy Procedures set forth herein only apply to the protection of patient information in these chapter 11 cases.

and managing their properties as debtors in possession pursuant to sections 1107(a) and 1108 of the Bankruptcy Code. Concurrently with the filing of this motion, the Debtors filed a motion requesting procedural consolidation and joint administration of these chapter 11 cases pursuant to Bankruptcy Rule 1015(b). No request for the appointment of a trustee or examiner has been made in these chapter 11 cases, and no official committee of unsecured creditors has been appointed in these chapter 11 cases.

6. The Debtors are a molecular diagnostic company that develops and markets novel non-invasive genomics tests to aid in the evaluation and management of melanoma. The Debtors' flagship product is their DermTech Melanoma Test™ (the "DMT"), a laboratory developed scalable genomics assay to clinically assess pigmented skin lesions for melanoma using non-invasive collection of patient samples using adhesive patches known as the DermTech Smart Sticker™ (together with the DMT and the Debtors' assays, the "Products"). In contrast to the existing standard of care of using a scalpel to biopsy suspicious lesions, the Products provide an objective, non-invasive, higher negative predictive value, and lower cost means of assessing pigmented lesions suspicious of melanoma and guiding the clinician's decision of whether to biopsy. The DMT has been demonstrated to rule out melanoma with a negative predictive value of 99%. The DMT is performed in the Debtors' molecular laboratory in San Diego, California. The Debtors also provide research laboratory services to several pharmaceutical companies which access the Debtors' technology on a contract basis to further clinical trials and studies related to other skin diseases and to measure the response of drugs under development.

7. Additional factual background regarding the Debtors, including their business operations, their corporate and capital structure, and the events leading to the filing of these chapter

11 cases, is set forth in detail in the First Day Declaration, filed concurrently herewith and incorporated herein by reference.

B. Specific Background

8. As described more fully in the First Day Declaration, the Debtors have historically offered the Products to healthcare practitioners or healthcare systems. Physicians, or other healthcare providers, requisition or prescribe a laboratory test for their patients from the Debtors, and the Debtors perform the laboratory test and provide test results back to the healthcare provider. In the ordinary course of business, the Debtors have access to and receive a patient's "protected health information" that the Debtors are required to confidentially maintain pursuant to the Health Insurance Portability and Accountability Act of 1996⁴ and corresponding privacy rules⁵ ("HIPAA"). The Debtors are continuing to process clinical tests during these chapter 11 cases.

THE PROPOSED PRIVACY PROCEDURES

9. While the Debtors do not presently anticipate a need to send notices in these cases to patients, it is critically important that patients and healthcare providers have certainty that all protected health information ("PHI") will be protected during these proceedings. Out of an abundance of caution, the Debtors request that the Court establish the following procedures (the "Privacy Procedures") to balance the need to protect patient health information pursuant to HIPAA with any requirement that would otherwise exist to publicly disclose information regarding these chapter 11 cases:

- (a) to the extent necessary, the Debtors shall be authorized, but not directed, to identify current or former patients in their Schedules of Assets and Liabilities (the "Schedules") and the Statements of Financial Affairs (the "Statements," and together with the Schedules, the "Schedules and Statements") solely by a code number, such as "Patient 1," "Patient 2," and so forth, and shall make an unredacted

⁴ 42 Pub. L. No. 104-191, 110 Stat. 1936 (codified as amended in scattered sections of 42 U.S.C.)

⁵ 45 C.F.R. pts. 160, 164.

copy of the Schedules and Statements available upon request to (i) the Court and to the Office of the United States Trustee for the District of Delaware (the “U.S. Trustee”), and (ii) any statutory committee appointed in these chapter 11 cases, only after entry into a mutually acceptable non-disclosure agreement that complies with HIPAA’s protected health information requirements, and (iii) any other party-in-interest only after the Court has entered an order, after notice and a hearing, authorizing and directing the Debtors to do so⁶ ((i) through (iii), the “Disclosure Procedures”);

(b) to the extent that service of current or former patients becomes necessary during these chapter 11 cases, the Debtors or their claims and noticing agent shall be authorized, but not directed, to maintain a list of all of the current or former patients (the “Patient List”) that appear on the matrix of creditors or are otherwise served with pleadings, as applicable, and shall make the Patient List, or any portion thereof, available in accordance with the Disclosure Procedures; and

(c) to the extent that the Debtors serve any document or pleading upon any person listed on the Patient List during the course of these chapter 11 cases, the Debtors shall note in the respective certificate of service that the parties served include persons listed on the Patient List.

BASIS FOR RELIEF

10. It is of paramount importance to the Debtors that PHI be maintained during these chapter 11 cases in accordance with HIPAA and patient and physician expectations. HIPAA imposes stringent standards on health care providers regarding the use and disclosure of patients’ health information and establishes significant penalties for unauthorized use or disclosure of such information. Because the Debtors may qualify as a health care provider which transmits health information electronically, they may also qualify as a “covered entity” subject to HIPAA. *See* 42 U.S.C. § 1320d-1(a)(3); 45 C.F.R. §§ 160.103, 164.104(3).

11. Under HIPAA, the Debtors may not disclose, except in limited circumstances, “individually identifiable health information.” *See* 45 C.F.R. § 164.502. HIPAA defines “individually identifiable health information” as:

⁶ *See* 45 C.F.R. 164.512(e)(1)(i) (permitting the disclosure of certain information protected by HIPAA pursuant to a Court order, provided that the covered entity discloses only information expressly authorized by such order).

any information, including demographic information collected from an individual, that—

(A) is created or received by a health care provider, health plan, employer, or health care clearinghouse; and

(B) relates to the past, present, or future physical or mental health or condition of an individual, the provision of health care to an individual, or the past, present, or future payment for the provision of health care to an individual, and—

(i) identifies the individual; or

(ii) with respect to which there is a reasonable basis to believe that the information can be used to identify the individual.

42 U.S.C. § 1320d(6); *see* 45 C.F.R. § 160.103 (utilizing same definition).

12. The Debtors could be subjected to significant penalties for the unauthorized disclosure of PHI. *See* 42 U.S.C. §§ 1320d-5 (establishing civil penalties for HIPAA violations), 1320d-6 (establishing criminal penalties for HIPAA violations); and 45 C.F.R. § 160.404 (setting forth the amount of civil penalties for HIPAA violations). Certain penalties can be imposed even if a person “did not know and, by exercising reasonable diligence, would not have known” that a violation occurred. *See* 45 C.F.R. § 160.404(b)(2)(i).

13. The requirements to maintain patient confidentiality under HIPAA could potentially conflict with the requirements to disclose certain information under the Bankruptcy Code. While it is far from clear which, if any, patients could be creditors in these cases, to the extent any could be required to be listed on any documents filed in these chapter 11 cases, their PHI must be protected. Therefore, the Debtors respectfully request that PHI be protected through the proposed Privacy Procedures pursuant to section 107(c) of the Bankruptcy Code, which allows the Court, for cause, to protect an individual if disclosure would create an undue risk of unlawful injury. *See* 11 U.S.C. § 107(c); *see also* Bankruptcy Rule 9018 (allowing a bankruptcy court to protect governmental matters that are made confidential by statute or regulation).

14. The Court may also approve the proposed Privacy Procedures pursuant to section 105(a) of the Bankruptcy Code, which authorizes the court to “issue any order, process, or judgment that is necessary or appropriate to carry out the provisions of this title.” 11 U.S.C. § 105(a).

15. The Debtors believe that the relief requested herein appropriately balances the need to maintain confidential patient information under HIPAA with the Debtors’ potential disclosure requirements under the Bankruptcy Code. Given the nature of any information that may reveal even the identity of patients, confidentiality in this context is of paramount importance.

NOTICE

16. The Debtors will provide notice of this Motion to: (a) the Office of the United States Trustee for the District of Delaware; (b) the United States Attorney’s Office for the District of Delaware; (c) the Internal Revenue Service; (d) the United States Securities and Exchange Commission; (e) the holders of the thirty (30) largest unsecured claims against the Debtors on a consolidated basis; (f) the state attorneys general for all states in which the Debtors conduct business; and (g) any party that has requested notice pursuant to Bankruptcy Rule 2002. The Debtors will serve copies of this Motion and any order entered in respect hereto as required by Local Rule 9013-1(m). The Debtors respectfully submit that, in light of the nature of the relief requested, no further notice is necessary.

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WHEREFORE, for the reasons set forth herein, the Debtors respectfully request that the Court (a) enter the Proposed Order substantially in the form annexed as **Exhibit A** hereto granting the relief requested herein and (b) grant such other and further relief as the Court may deem just and proper.

Dated: June 18, 2024
Wilmington, Delaware

WILSON SONSINI GOODRICH & ROSATI, P.C.

/s/ Shane M. Reil

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Proposed Counsel to the Debtors and Debtors in Possession

Exhibit A

Proposed Order

**IN THE UNITED STATES BANKRUPTCY COURT
FOR THE DISTRICT OF DELAWARE**

In re:

DERMTECH, INC., *et al.*,¹

Debtors.

Chapter 11

Case No. 24-11378 ([____])

(Jointly Administered)

Ref. Docket No. ____

**ORDER (I) AUTHORIZING DEBTORS TO IMPLEMENT CERTAIN
PROCEDURES TO MAINTAIN THE CONFIDENTIALITY OF PATIENT
INFORMATION AS REQUIRED BY APPLICABLE PRIVACY
RULES; AND (II) GRANTING RELATED RELIEF**

Upon the motion (the “Motion”) of the above-captioned debtors and debtors in possession (collectively, the “Debtors”) for entry of an order (this “Order”) (i) authorizing the Debtors to implement certain procedures to maintain the confidentiality of patient information as required by applicable privacy rules; and (ii) granting related relief; and this Court having found that it has jurisdiction over this matter pursuant to 28 U.S.C. §§ 1334(b) and 157, and the Amended Standing Order of Reference from the United States District Court for the District of Delaware, dated February 29, 2012; and this Court having found that venue of these chapter 11 cases and the Motion in this district is proper pursuant to 28 U.S.C. §§ 1408 and 1409; and this Court having found that this matter is a core proceeding pursuant to 28 U.S.C. § 157(b); and this Court having found that notice of the Motion has been given as set forth in the Motion and that such notice is adequate and no other or further notice need be given; and this Court having determined that it may enter a final order consistent with Article III of the United States Constitution; and this Court having found and determined that the relief sought in the Motion is in the best interests of the Debtors, their estates,

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their creditors and all other parties in interest, and that the legal and factual bases set forth in the Motion establish just cause for the relief granted herein; and after due deliberation and sufficient cause appearing therefor,

IT IS HEREBY ORDERED THAT:

1. The Motion is GRANTED as set forth herein.
2. The following procedures (the “Privacy Procedures”) shall apply in these chapter

11 cases:

(a) to the extent necessary, the Debtors shall be authorized, but not directed, to identify current or former patients in their Schedules of Assets and Liabilities (the “Schedules”) and the Statements of Financial Affairs (the “Statements,” and together with the Schedules, the “Schedules and Statements”) solely by a code number, such as “Patient 1,” “Patient 2,” and so forth, and shall make an unredacted copy of the Schedules and Statements available upon request to (i) the Court and to the Office of the United States Trustee for the District of Delaware, and (ii) any statutory committee appointed in these chapter 11 cases, only after entry into a mutually acceptable non-disclosure agreement that complies with HIPAA’s protected health information requirements, and (iii) any other party-in-interest only after the Court has entered an order, after notice and a hearing, authorizing and directing the Debtors to do so² ((i) through (iii), the “Disclosure Procedures”);

(b) to the extent that service of current or former patients becomes necessary during these chapter 11 cases, the Debtors or their claims and noticing agent shall be authorized, but not directed, to maintain a list of all of the current or former patients (the “Patient List”) that appear on the matrix of creditors or are otherwise served with pleadings, as applicable, and shall make the Patient List, or any portion thereof, available in accordance with the Disclosure Procedures; and

(c) to the extent that the Debtors serve any document or pleading upon any person listed on the Patient List during the course of these chapter 11 cases, the Debtors shall note in the respective certificate of service that the parties served include persons listed on the Patient List.

² See 45 C.F.R. 164.512(e)(1)(i) (permitting the disclosure of certain information protected by HIPAA pursuant to a Court order, provided that the covered entity discloses only information expressly authorized by such order).

3. The Debtors' compliance with the foregoing Privacy Procedures shall constitute compliance with section 521 of the Bankruptcy Code, Bankruptcy Rule 1007(a), and Local Rule 1007.

4. The Debtors are authorized to take all actions necessary to effectuate the relief granted by this Order in accordance with the Motion.

5. Notwithstanding the possible applicability of Bankruptcy Rules 7062, 9014 or otherwise, this Order shall be immediately effective and enforceable upon its entry.

6. This Court shall retain jurisdiction with respect to all matters arising from or related to the interpretation, implementation, or enforcement of this Order.